

PTO/SB/21 (08-03)

Approved for use through 08/30/2003. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

<b>TRANSMITTAL FORM</b> (to be used for all correspondence after initial filing)	Application Number	10/619,777
	Filing Date	July 15, 2003
	First Named Inventor	W.H. ROARK
	Art Unit	1614
	Examiner Name	
Total Number of Pages in This Submission	Attorney Docket Number	PC25131A

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Copies of Cited Art Return Postcard
<b>Remarks</b>		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	Claude F. Purchase, Jr.
Signature	<i>Claude F. Purchase Jr.</i>
Date	January 16, 2004

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Typed or printed name	Virginia J. Cook		
Signature	<i>Virginia J. Cook</i>	Date	January 16, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PC25131A

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANT : WILLIAM HOWARD ROARK EXAMINER : UNKNOWN  
SERIAL NO. : 10/619,777 ART UNIT : 1614  
FILED : JULY 15, 2003 CONFIRM. NO. : 8783  
FOR : COMBINATION OF AN ALLOSTERIC ALKYNE INHIBITOR  
OF MATRIX METALLOPROTEINASE-13 WITH CELECOXIB  
OR VALDECOXIB

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97-1.98**

Commissioner for Patents  
PO BOX 1450  
Alexandria, VA 22313-1450

Dear Sir:

This paper is an Information Disclosure Statement Under 37 C.F.R. §§ 1.97-1.98  
for the above-identified patent application.

**Remarks** start on page 2.

**REMARKS**

Claims 1-10 are pending in the application.

The currently pending claims are directed to a combination comprising valdecoxib, or a pharmaceutically acceptable salt thereof, and an allosteric alkyne inhibitor of MMP-13, or a pharmaceutically acceptable salt thereof, a pharmaceutical composition comprising the combination, and a method of treating a disease or disorder using the combination. Applicants' instant paper does not amend the claims.

***Information Disclosure Statement***

Applicant herein makes available to the Patent and Trademark Office the art cited in the enclosed Information Disclosure Statement ("IDS") on Form(s) PTO/SB/08A and/or PTO/SB/08B. Copies of U.S. patents and patent application publications, if any, cited in the IDS are not provided. Applicant understands that the Patent and Trademark Office has asked that they not be provided in view of their ready availability to the Examiner via electronic means. Copies of all other cited art are provided.

Applicant also makes available to the Patent and Trademark Office the following co-pending applications:

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/620,174

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC INHIBITOR OF MATRIX

METALLOPROTEINASE-13 WITH CELECOXIB OR VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25036A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,662

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC CARBOXYLIC INHIBITOR OF  
MATRIX METALLOPROTEINASE-13 WITH CELECOXIB OR  
VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25132A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,663

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC INHIBITOR OF MATRIX  
METALLOPROTEINASE-13 WITH A SELECTIVE INHIBITOR OF  
CYCLOOXYGENASE-2 THAT IS NOT CELECOXIB OR VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25207A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/620,173

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC ALKYNE INHIBITOR OF MATRIX  
METALLOPROTEINASE-13 WITH A SELECTIVE INHIBITOR OF  
CYCLOOXYGENASE-2 THAT IS NOT CELECOXIB OR VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25208A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,769

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC CARBOXYLIC INHIBITOR OF  
MATRIX METALLOPROTEINASE-13 WITH A SELECTIVE INHIBITOR OF  
CYCLOOXYGENASE-2 THAT IS NOT CELECOXIB OR VALDECOXIB

ART UNIT: 1614

APPLICANT'S DOCKET NO.: PC25209A

The Examiner is respectfully requested to consider carefully the complete text of the cited references in connection with the examination of the above-identified application in accord with 37 CFR §1.104(a), including consideration of the claims.

It is respectfully requested that all cited references considered by the Examiner be listed in the "References Cited" portion of any patent issuing from the instant application (MPEP § 1302.12).

The Commissioner is hereby authorized to charge any other fees that may be required, or credit any overpayment, to deposit account number 23-0455.

The undersigned would welcome a telephone call from the Office to discuss any matters.

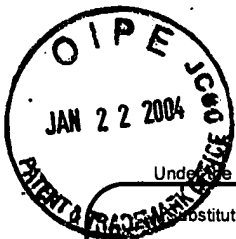
Respectfully submitted,

Date:

January 16, 2004

Claude F. Purchase, Jr.  
Claude F. Purchase, Jr.  
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Enc.



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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/619,777
Filing Date	July 15, 2003
First Named Inventor	W. H. Roark
Art Unit	1614
Examiner Name	
Attorney Docket Number	PC25131A

Sheet 1

of 8

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 2003/0078276 A1	04-24-2003	ANDRIANJARA, ET AL	
		US- 2003/0130278 A1	07-10-2003	GAUDILLIERE, ET AL	
		US- 2003/0144274 A1	07-31-2003	BUNKER, ET AL	
		US- 6008243	12-28-1999	BENDER, ET AL	
		US- 5948780	09-07-1999	PETERSON, ET AL	
		US- 2002/0156061 A1	10-24-2002	BARVIAN ET AL	
		US- 2002/0151558 A1	10-17-2002	ANDRIANJARA, ET AL	
		US- 2002/0156069 A1	10-24-2002	PICARD ET AL	
		US- 2002/0151555 A1	10-17-2002	BARVIAN ET AL	
		US- 2002/0161000A1	10-31-2002	BARVIAN ET AL	
		US- 6225311 B1	05-01-2001	LEVIN ET AL	
		US- 5929097	07-27-1999	LEVIN ET AL	
		US- 4818819	04-04-1989	E.C. TAYLOR ET AL	
		US- 4902796	02-20-1990	E.C. TAYLOR ET AL	
		US- 5646141	07-08-1997	M.D. VARNEY ET AL	
		US- 4412856	11-01-1983	BRUNNER ET AL	
		US- 5990116	11-23-1999	NUSSBAUMER	
		US-			
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		WO 03/032999 A1	04-24-2003	BUNKER ET AL		
		WO 03/033478 A1	04-24-2003	GAUDILLIERE ET AL		
		WO99/52910 A1	10-21-1999	ROBINSON, Ralph		
		WO 00/37107 A2	06-29-2000	MCKEARN ET AL		
		WO 02/064080 A2/A3	08-22-2002	ANDRIANJARA ET AL		
		WO 00/09485 A1	02-24-2000	MCCLURE ET AL		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**Complete if Known**

*(Use as many sheets as necessary)*

Sheet 2

of 8

Application Number	10/619,777
Filing Date	July 15, 2003
First Named Inventor	W.H. Roark
Art Unit	1614
Examiner Name	
Attorney Docket Number	PC25131A

[illegible]

FOREIGN PATENT DOCUMENTS						T <sup>9</sup>
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
		WO0155133 A1	08-02-2001	WATANABE ET AL		
		WO0206513 A2	01-24-2002	HOMA ET AL		
		WO9616046 A2/A3	05-30-1996	GUERRY ET AL		
		WO0040561 A1	07-13-2000	TURNER ET AL		
		WO9816514 A1	04-23-1998	LEVIN ET AL		

Date  
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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
		WO0035906 A2	06-22-2000	LUK ET AL		
		WO0163244 A1	08-30-2001	CHEN ET AL		
		WO02064599 A1	08-22-2002	DYER ET AL		
		WO02064547 A2/A3	08-22-2002	BARVIAN ET AL		
		WO02064598 A1	08-22-2002	HARTER ET AL		

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of 8

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		Country Code <sup>3</sup> ~Number <sup>4</sup> ~Kind Code <sup>5</sup> (if known)				
		WO02064572 A1	08-22-2002	ANDRIANJARA ET AL		
		WO02064595 A1	08-22-2002	ANDRIANJARA ET AL		
		WO02064578 A1	08-22-2002	PICARD ET AL		
		WO02064571 A1	08-22-2002	BARVIAN ET AL		
		WO02064568 A1	08-22-2002	BARVIAN ET AL		
		WO0112611 A1	02-22-2001	BLAGG		

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Signature**

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Sheet	5	of	8
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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
		WO0234726 A3/A2	05-02-2002	NOE ET AL		
		WO0234753 A2	05-02-2002	BRONK ET AL		
		EP0935963 A2/A3	08-18-1999	MCCLURE ET AL		
		EP 1138680 A1	10-04-2001	NOE		
		WO01/053274 A1	07-26-2001	BENDER ET AL		
		WO9633181 A1	10-24-1996	NAKAYAMA ET AL		

**Examiner  
Signature**

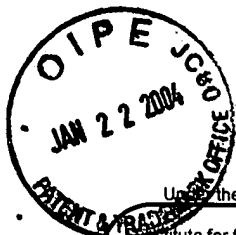
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Attorney Docket Number	PC25131A
Sheet 7 of 8	

**NON PATENT LITERATURE DOCUMENTS**

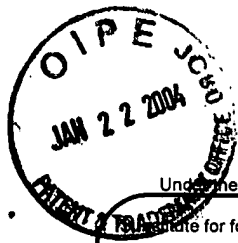
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		MICHAEL G. NATCHUS, et al., "Development of New Carboxylic Acid-Based MMP Inhibitors Derived from Functionalized Propargylglycines", J.Med.Chem. 2001, 44:1060-1071.	
		International Search Report for International Application No. PCT/IB03/03154	
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**Complete if Known**

Application Number 10/619,777

Filing Date July 15, 2003

First Named Inventor W.H. Roark

Art Unit 1614

Examiner Name

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of 8

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		CLARK, et al., "Matrix metalloproteinase inhibitors in the treatment of arthritis", Current Opinion in Anti-inflammatory & Immunomodulatory Investigational Drugs 2000, 2(1):16-25	
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